

**Scientific Considerations Related to
Developing Follow-on Protein Products
Public Workshop
September 14-15, 2004**

AGENDA

Day 1 - September 14, 2004

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|--|---|
| 8:30 Introduction | Ajaz Hussain, Ph.D.,
Deputy Director, Office of
Pharmaceutical Science, CDER |
| 8:40 Opening Remarks | Janet Woodcock, M.D.
Acting Deputy Commissioner for
Operations, FDA |
| 8:50 Opening Remarks | Jesse Goodman, M.D.
Director, CBER |
| 9:00 Terminology | Keith Webber, Ph.D.
Acting Director, Office of
Biotechnology Products, OPS/CDER |
| 9:45 General Panel | |
| 10:45 Break | |
| 11:00 Panel #1 - Manufacturing Issues | |
| 12:30 Lunch (on your own) | |
| 1:30 Panel # 2 - Characterization Issues | |
| 3:30 Break | |
| 3:45 Panel # 3 - Potency and Surrogates for
Efficacy and Safety | |
| 4:55 Closing Remarks | Ajaz Hussain, Ph.D.
Deputy Director, Office of
Pharmaceutical Science CDER |
| 5:00 End of first day | |

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Day 2 - September 15, 2004

8:00 Introduction to Day 2

Ajaz Hussain, Ph.D.
Deputy Director, Office of
Pharmaceutical Science CDER

8:15 Panel # 4 - Immunogenicity Issues

9:15 Break

9:30 Panel # 5 - Preclinical and Clinical Issues

11:30 Closing Remarks

Ajaz Hussain, Ph.D.
Deputy Director, Office of
Pharmaceutical Science CDER

12:00 End of second day